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REMARKS

Claims 1-89 were pending in the application. Claims 1, 9, 16, and 29-31 have been amended. Upon entry of this amendment claims 1, 7-10, 12-25, and 29-33 will be pending.

Amendments to claims 1, 9, 16, and 29-31 do not present new issues requiring further consideration or search. The amendments also present the claims in better form in case of appeal (37 C.F.R. § 1.116 (b)). Therefore, Applicants respectfully request the entry of the amendments.

No new matter has been added.

Objections

Claims 9, 10, 12-24, and 30-33 stand objected to because, according to the Office, "claim 9 should be amended to recite 'the nucleic acid molecule' instead of 'a nucleic acid molecule' and claim 16 should be amended to recite 'the expression vector' instead of 'an expression vector." (Office Action, page 2). Claims 10, 12-15, 17-24 and 30-33 are also objected to. As suggested by the Office, Applicants have amended claims 9 and 16 to replace "a" with "the."

Claim 29 stands objected to because, according to the Office "the syntax could be improved." Applicants have amended claim 29 to improve the claim's syntax.

Claims 30 and 31 stand objected to for the use of the term "recombinant" because it allegedly lacks antecedent basis. Applicants have amended claims 30 and 31 to remove the term "recombinant" and have also replaced "a" with "the."

In view of the foregoing, Applicants respectfully request that the objections be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1, 7-9, 12-24, 29, and 30 remain rejected under 35 U.S.C. § 102 as allegedly anticipated by Glucksmann *et al.* (U.S. Patent Application 2002/015046 A1). Applicants respectfully disagree.

The standard for anticipation under 35 U.S.C. § 102 is one of strict identity. An anticipation rejection requires a showing that each limitation of a claim be found in a single reference, *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984).

The Office alleges that Glucksmann discusses a nucleic acid molecule that is 98.8% identical to that encoding SEQ ID NO:25 of the present invention. As amended, claim 1 recites a nucleic acid molecule that encodes a protein comprising an amino acid sequence of SEQ ID NO: 25. Glucksmann fails to teach or even suggest a nucleic molecule that encodes a protein that comprises an amino acid sequence of SEQ ID NO:25 or a nucleic acid molecule that comprises SEQ ID NO:12. Therefore, Glucksmann fails to anticipate claims 1, 7-9, 12-24, 29, and 30.

In view of the foregoing, Applicants respectfully request that the rejection of claims 1, 7-9, 12-24, 29, and 30 under 35 U.S.C. § 102 (e) be withdrawn.

Rejection under 35 U.S.C. § 101

Claims 1, 7-10, 12-25, and 29-33 remain rejected under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by a specific, substantial and credible asserted utility or a well established utility. The Office alleges that the arguments presented by Applicants in response to the previous Office Action, although considered, were not deemed persuasive. Applicants respectfully disagree.

The Utility Examination Guidelines require a claimed invention have a specific, substantial and credible asserted utility, or, alternatively a well-established utility. As Applicants have asserted utilities that are specific, substantial and credible, and well established, the Utility Requirement has been satisfied. Applicants therefore respectfully request the withdrawal of the rejection under 35 U.S.C. § 101.

To meet the utility requirement, the invention must be "practically useful," *Anderson v Natta*, 480 F.2d 1392, 1397 (CCPA 1973) and confer a "specific benefit" on the public. *Brenner v. Manson*, 383 U.S. 519, 534 (1966). The threshold of utility under this standard is not high, and requires merely an "identifiable" benefit. *Juicy Whip Inc. v.*

Orange Bang Inc., 51 USPQ2d 1700 (Fed. Cir. 1999). In *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991), the CAFC explained that "An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding lack of utility." *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 762, 221 USPQ 473, 480 (Fed. Cir. 1984).

Inventions that achieve a practical use, a use that is also achieved by other inventions, satisfy the utility requirement. Thus, practical utilities can be directed to classes of inventions, so long as a person of ordinary skill in the art would understand how to achieve a practical benefit from knowledge of the class. *Montedison*, 664 F.2d at 374-75. For example, many materials conduct electricity. This general utility applies to a broad class of inventions (conductive materials) and satisfies the utility requirement of section 101. The fact that other materials also conduct electricity does ***not*** mean that other materials that conduct electricity want for utility. What is important, however, is that G-protein coupled receptors are known to have practical uses well beyond throwaway uses like snake food.

The Office appears to be under the mis-impression that inventions that are, *inter alia*, useful for use in research, are unpatentable. This is simply not true. The Patent Office's patent database is replete with patents claiming useful research tools, e.g., spectrophotometers. A material whose only use is as a tool in research may indeed be patentable. *Brenner* excludes only those research purposes where the only use of the material itself is as the subject of research. If *Brenner* had held otherwise, any chemical material would, by virtue of its existence, be useful. However, nowhere do those cases state or imply that a material cannot be patentable if has some other beneficial use in research.

The Office also alleges that although using the protein to identify ligands is credible

> it is not substantial nor specific to the protein of the present invention. The specification does not characterize the polypeptide encoded by the polynucleotide of the claimed

> invention. Therefore, binding sites, etc. are not identified. Significant further experimentation would be required of the skilled artisan to characterize the protein and search for ligands. There is no disclosure, for example, of how to assay for ligand binding and possible transduction mechanisms.

(Office Action, page 4). Applicants respectfully disagree.

Applicants have described how to assay for ligand binding and possible transduction mechanisms (see, for example, pages 41-53, and Examples 11-13). Without the present invention (*i.e.* the discovery of the polynucleotide that encodes the polypeptide), none of these assays could be performed using the polypeptide that is encoded by the polynucleotide of the present invention. As discussed above, the utility requirement does not prevent an invention that is to be used as a research tool from being patented.

Assay methods, like many other tools used in research, have an immediately realizable "real world" value. For example, an assay method that can identify chemical compounds that possess a particular physical, structural or biological property clearly has "real world" value irrespective and independent from the utility that may be associated with the compounds identified using the assay method. As a consequence, a presumption that assay methods cannot possess utility if the compound isolated or identified using the assay do not have utility would be the product of a flawed analysis of *Brenner*. Such a conclusion also would suggest that processes and products can never possess utility if their utility lies in the field of research. Indeed, the application of this concept of the utility requirement as it relates to methods for assaying or identifying compounds, if taken literally, would mean that claims to methods such as NMR, infrared, x-ray crystallography, and screening for other important biological properties, would be unpatentable because further research would be necessary to establish utility for the compounds identified or assayed. This certainly cannot be the result intended by the Patent Office when issuing these guidelines.

Antibodies specific for G-protein coupled receptors can also be used, for example, to study protein expression and localization, even in cases where little is known as to how

a particular G-protein coupled receptor works. No additional experimentation would be required, therefore, to determine whether a G-protein coupled receptor has a practical use as all G-protein coupled receptors have at least one practical use.

Because all G-protein coupled receptors, as a class, convey practical benefit (much like the class of DNA ligases identified in the Training Materials), there should be no need to provide additional information about them. A person of ordinary skill in the art need not guess whether any given GPCR conveys a practical benefit. Nor is it necessary to know how or why any given GPCR works. It is settled law that how or why any invention works is irrelevant to determining utility under 35 U.S.C. §101: "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *In re Cortwright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999)(quoting *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

Applicants need only prove a "substantial likelihood" of utility; certainty is not required. *Brenner*, 383 U.S. at 532. The amount of evidence required to prove utility depends on the facts of each particular case. *In re Jolles*, 628 F.2d 1322, 1326 (CCPA 1980). "The character and amount of evidence may vary, depending on whether the alleged utility appears to accord with or to contravene established scientific principles and beliefs." *Id.* Unless there is proof of "total incapacity," or there is a "complete absence of data" to support the applicant's assertion of utility, the utility requirement is met. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992); *Envirotech*, 730 F.2d at 762. The Office has failed to provide proof of "total incapacity", and Applicants have provided information that supports the asserted utilities.

Additionally, as discussed in Applicants' previous response, the Utility requirement may also be satisfied by an "Art Established Utility" which means that "a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention... and the utility is specific, substantial and credible." (M.P.E.P. §2107).

To further support Applicants assertion that there is an "Art Established Utility," Applicants point out that commercial products relating to GPCRs for which no confirmed

function has been identified are commercially available. GPCRs, ORF clones of GPCRs, and antibodies that bind to GPCRs are commercially available. For example, Applicant points out that FabGennix Inc. of Shreveport, Louisiana sells an antibody directed to Retinal Anti-GP75. GPCR75 is said to be a GPCR for which a ligand has not yet been identified (*see* attached product sheet). Invitrogen sells ORF clones of GPCRs including those for which a ligand has not yet been identified (*see* attached list, especially noting Clone Ids IOH22483, IOH14039, IOH13056, IOH22637, IOH13239, and IOH13516). MD Bio of Taiwan sells GPCR peptides and antibodies against such peptides, again where no ligand has yet been identified. That at least three companies make and sell such GPCR products proves that there is a well-established utility for the presently claimed GPCR polypeptides. Accordingly there could be no better proof of the utilities of the claimed polypeptides- such products are made by a manufacturer (who expects to sell them) for consumers (who expect to buy them). Any argument that there is no art-recognized utility for such polypeptides, and the polynucleotides that encode them, seems meritless.

In view of the foregoing, Applicants respectfully requests that the rejection under 35 U.S.C. § 101 be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 1, 7-10, 12-25 and 29-33 remain rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to adequately teach how to use the instant invention.

As discussed above, the present invention *is* supported by a specific, substantial, and credible asserted utility as well as a well established utility. Accordingly, Applicants respectfully request that the rejection be withdrawn.

The Office also alleges, that "even if the present invention possessed utility under 35 U.S.C. § 101, claims 1, 7-9, 12-24, 29 and 30 would still remain rejected under 35 U.S.C. § 112, first paragraph, regarding the term '99% homologous,' because one of skill in the art would allegedly not know how to make and/or use the present invention and

that the present invention is not adequately described. Applicants respectfully disagree. However, in order to further prosecution, Applicants have amended the claims to recite a polypeptide that comprises SEQ ID NO:25. One of skill in the art, given the teachings of the present invention, would be able to make and use the claimed invention. Also, the art skilled would be able to envision the defining characteristics, identifying features, and structure of the claimed subject matter.

In view of the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6928 to clarify any unresolved issues raised by this response.

Respectfully submitted,

Daniel M. Scolnick, Ph.D.
Reg. No. 52,201

Date: **November 17, 2003**

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Philadelphia, PA 19103-3508
Telephone: (215) 665-2000
Facsimile: (215) 665-2013

Attachments: Product Sheet for Anti-GPCR-75 Antibodies
Product sheet for GPCR control peptides and antibodies (MD Bio)
Product sheet for GPCR ORF clones (Invitrogen)

Ultimate™ ORF Browser Results

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33 total records for G-Protein Coupled Receptors

Buy	Clone ID	Species	Definition	Gene Symbol
☐	IOH3294	Human	complement component 5 receptor 1 (C5a ligand); complement component-5 receptor-2 (C5a ligand)	C5R1
☐	IOH12614	Human	purinergic receptor P2Y, G-protein coupled, 11	P2RY11
☐	IOH22481	Human	clone MGC:33224 IMAGE:5267661, mRNA, complete cds.	RDC1
☐	IOH14039	Human	Similar to putative nuclear protein ORF1-FL49	ORF1-FL49
☐	IOH11484	Human	glycoprotein Ib (platelet), alpha polypeptide	GP1BA
☐	IOH1987	Human	tachykinin receptor 1 isoform short; NK-1 receptor; Tachykinin receptor 1 (substance P receptor; neurokinin-1 receptor); tachykinin 1 receptor (substance P receptor, neurokinin 1 receptor); neurokinin 1 receptor	TACR1
☐	IOH13056	Human	similar to POSSIBLE GUSTATORY RECEPTOR CLONE PTE01	LOC11513
☐	IOH9916	Human	coagulation factor II (thrombin) receptor-like 1	F2RL1
☐	IOH9624	Human	vasoactive intestinal peptide receptor 2	VIPR2
☐	IOH10678	Human	endothelin receptor type A	EDNRA
☐	IOH22437	Human	Similar to parathyroid hormone receptor 1, clone MGC:34582 IMAGE:5180885, mRNA, complete cds.	PTHR1
☐	IOH13583	Human	Duffy blood group	FY
☐	IOH4585	Human	cholecystokinin B receptor	CCKBR
☐	IOH11033	Human	endothelial differentiation, lysosphosphatidic acid G-protein-coupled receptor, 4; G protein-coupled receptor; LPA receptor EDG4; Lysophosphatidic acid receptor EDG4	EDG4
☐	IOH10868	Human	CD97 antigen isoform 2 precursor; leukocyte antigen CD97; seven-span transmembrane protein	CD97
☐	IOH22632	Human	formyl peptide receptor-like 1; lipoxin A4 receptor (formyl peptide receptor related)	FPRL1
☐	IOH22669	Human	adrenomedullin receptor	ADMR
☐	IOH13339	Human	super conserved receptor expressed in brain 3	SREB3

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New Item

Novel Orphan retinal G-protein coupled Receptor (GPCR-75) selective antibodies

Anti-GPCR-75Antibodies (GPCR75-100P, GPCR75-101AP and GPCR75-112AP)

Recently a novel human G-protein coupled receptor gene has been characterized and mapped to chromosome 2p16. This gene codes for a 540 amino acid protein in retinal pigment epithelium (RPE) and cells surrounding retinal arterioles. In contrast, the Northern blot data obtained from mouse sections suggest the expression of transcripts in photoreceptor inner segments and I outer plexiform layer. The transcripts of the GPCR-75 gene (7kb) are also found in abundance in brain sections. So far, no mutations in GPCR-75 protein were identified in patients suffering from Doyne's honeycomb retinal dystrophy (DHRD), an inherited retinal degeneration disease that maps to chromosome 2p16 (1).

The GPCR-75 protein is approximately 78 kDa (540 amino acids) protein that is primarily expressed in human retinal pigment epithelium (RPEs). The GPCR-75 sequence analyses suggest the presence of 7 trans-membrane domains, a characteristic feature of GPCR. The protein has putative N-glycosylation sites near the extra cellular N-terminal end of the proteins. The protein has a large 3 intra cellular loop which might be the site for interaction of G-proteins. The short carboxy terminal is intracellular and has putative post-translational modification lipid modification sites.

The Anti-GPCR-75-selective antibodies were generated against conserved sequences near N- and C-termini of the protein that are unique to GPCR-75 protein. The polyclonal antibody strongly labels a 78 kDa protein in RPE cell extracts. Anti-GPCR-75-selective antibody is also available in affinity-purified form for confocal, Western blotting and immunocytochemical analyses. *FabGennix Int. Inc.* will also conjugate antibodies with fluorescent probes upon request at extra charge. *FabGennix Int. Inc.* will also provides antibodies against proteins that are involved in retinal degenerative diseases such as various Anti-PDE antibodies, Anti-MERTK, Anti-Phospho-MERTK, EGF-containing fibulin like extracellular protein (EFEMP1), Anti-Myocilin (TIGR), Anti-Bestrophin, Anti-ELVOL4 and a Usher syndrome specific Anti-USH2a antibodies etc. FabGennix Int. Inc employs cyclic peptide methodology for generating antibodies, which results in higher titer and specificity (2). FabGennix Int. Inc., will also provide Western blot positive controls for most of these antibodies in ready-to-use buffer for easy identification of respective proteins. Limited quantities of antigens are also available. Please enquire for their availability before ordering.

Catalog #	Host Species	Nature	Cross reactivity	Quantity	volume	Price
GPCR75-100P	Rabbit	Polyclonal antisera	R, M, H	100 ml	100 ul	$ 195.00
GPCR75-101AP	Rabbit	Affinity purified IgG	R, M, H	100 ug	150 ul	$ 225.00
GPCR75-112AP	Rabbit	Affinity purified IgG	R, M, H	100 ug	150 ul	$ 225.00
PC-GPCR75	N/A	WB positive control	Rat	For 5 App	50 ul	$ 75.00
P-GPCR75	N/A	Antigenic peptides	n/a	250 ug	inquire	$ 65.00

R = rat; M = mouse; H = human; C = chicken; monk = monkey ; * not all variants are labeled equally

Immunogen: Synthetic cyclic peptide (GPCR75-101AP = PNATSLHVPHSQSGNSTS-amide; GPCR75-112AP = STELQSGLQDLRHATLVTC-amide).

Concentration: GPCR75-101AP; GPCR-112AP IgG concentration 0.75-1.25 mg/ml in 50% antibody stabilization buffer.

Applications: Antibody GPCR75-100/GPCR75-101AP are ideal for WB, IMM and IHC assays. The dilutions for this antibody is for reference only. Investigators are expected to determine the optimal conditions for specific assay in his/her laboratory. Dilutions: WB > 1:500; Immunoprecipitation & Lp pull-down assays> 1:250

Reactivity: This antibody detects a single 78 kDa Orphan GPCR75 protein in human RPE cell extracts.

Protocols: Standard protocol for various applications (WB; IMM and IHC) of this antibody is provided with the product specification sheet, however, FabGennix Int. Inc. strongly recommends investigators to optimize conditions for use of this antibody in their laboratories.

Form/Storage: The antiserum is supplied in antibody stabilization buffer with 0.02% sodium azide or thimerosal/merthiolate as preservative. The affinity-purified antibodies are purified on antigen-apheresse affinity column and supplied as 1-1.25 mg/ml IgG in antibody stabilization buffer containing preservatives with low viscosity and cryogenic properties. For long-term storage of antibodies, store at -20°C. Now these antibodies can be stored at -20°C and used immediately with out thawing. FabGennix Inc. does not recommend storage of very dilute antibody solutions unless they are prepared in specially formulated multi use antibody dilution buffer (Cat # DiluOBuffer). Working solutions of antibodies in DiluOBuffer should be filtered through 0.45µ filter after every use for long-term storage.

78 kDa Orphan Receptor-75 in human RPE cells. Antibody GPCR-100P (1:400)

References:

1. Tartafin R. E., Kriechner L. S., Bollinghaus J., Baffi. J. Taymanns B. E., Gregor E. K., Cuoky K., Stratakis C. A., Gregory-Evans C. Y. Biochem. Biophys. Res. Commun. 260, 174-180, 1999.
2. Farooqui, S. M., Brock. W. J., A. Hamdi., Prasad. C. (1991) J. Neurochem. 57, 1363-1369.

* For users who may require large amounts of GPCR75-100P or GPCR75-101AP, please enquire about bulk material discounts.
This Product is for Research Use Only and is NOT intended for use in humans or clinical diagnosis.

061901-0020SF1001Z-rev10.00

FabGennix Inc.
INTERNATIONL
2940 Youree Drive, Suite E, Shreveport, LA 71104

生工有限公司

Rat Taste Receptor 2 (TR2) Antibodies

Rat Taste Receptor 2 (TR2) Antibodies

Cat. # TR21-P, Rat TR2 Control Peptide # 1, SIZE: 100 ug/100 ul
FORM: Œ Soln Œ Lyophilized Lot # 3113P

Cat. # TR21-S, Rabbit Anti-rat TR2 antiserum # 1, SIZE: 100 ul neat antiserum
FORM: Œ Soln Œ Lyophilized. Lot # 38889S

Cat. # TR21-A, Rabbit Anti-rat TR2 Ab # 1 (affinity pure) SIZE: 100 ug
FORM: Œ Soln Œ Lyophilized. Lot # 38889A

Higher vertebrates are believed to possess at least five basic tastes: Sweet, bitter, sour, salty, and unami (the taste of monosodium glutamate). Taste receptor cells that may selectively reside in various parts of the tongue and respond to different tastants and perceive these taste modalities. Circumvallate papillae, found at the very back of the tongue, are particularly sensitive to biter substances. Foliate papillae, found at the posterior lateral edge of the tongue, are sensitive to sour and bitter. Fungiform papillae at the front of the tongue specialize in sweet taste.

Recently, two novel taste receptors, TR1 and TR2, have been cloned with distinct topographical distribution in taste receptor cells and taste buds. TRs are members of a new group of 7 TM domain containing GPCR distantly related to other chemosensory receptors (Ca+-sensing receptor (CaSR, a family of putative hormone receptor (V2R), and metabotropic glutamate receptors). TR1 is expressed in all fungiform taste buds, whereas TR2 localized to the circumvallate taste buds. Both receptors do not co-localize with gustducin.

Source of Antigen and Antibodies

TR1 (rat 840 aa) and TR2 (rat 843 aa) share ~40% homology with each other, and ~30% with CaSR, and 22-30% with V2R pheromone receptors and mGLURs. Rat TR are 7 TM domain containing protein with an extra long N-terminal, extracellular domain (1). A 19 AA Peptide (designated TR21-P; control peptide) sequence near the C-terminus of rat TR2(1) was selected for antibody production. The peptide was coupled to KLH, and antibodies generated in rabbits. Antibody has been affinity purified using control peptide-Sepharose.

Form & Storage

Control peptide Solution is provided in PBS, pH 7.4 at 1 mg/ml (100 ug/100 ul). Antiserum is supplied as neat serum (100 ul soln or lyophilized). Affinity pure antibodies were purified over the peptide-Sepharose column and supplied as 1 mg/ml soln in PBS, pH 7.4 and 0.1% BSA as stabilizer (100 ul in solution or Lyophilized).
The peptides and antibodies also contain 0.1% sodium azide as preservative. Lyophilized products should be reconstituted in 100 ul water and gently mixed for 15 min at room temp. All peptide/antibody

received in solution or

reconstituted from lyophilized vials should be stored frozen at -20oC or below in suitable aliquots. It is not recommended to store diluted solutions. Avoid repeated freeze and thaw.

Recommended Usage

Western Blotting (1:1K-5K for neat serum and 1-10 ug/ml for affinity pure antibody using ECL technique).

ELISA: Control peptide can be used to coat ELISA plates at 1 ug/ml and detected with antibodies (1:10-50K for neat serum and 0.5-1 ug/ml for affinity pure).

Histochemistry & Immunofluorescence: We recommend the use of affinity purified antibody at 1-20 ug/ml in paraformaldehyde fixed sections of tissues (1).

Specificity & Cross-reactivity

The 19 AA rat TR21-P control peptide is specific for rat TR2. It has no significant sequence homology with TR1 or gustducin or pheromone receptors. Antibody cross-reactivity in various species has not been studied. The TR21-P control peptide is available to confirm specificity of antibodies.

References:

1. Hoon MA et al (1999) Cell 96, 541-555; Lindemann B (1999) Nature Med. 5, 381-382

"Neat Antisera" are the unpurified antiserum and it is suitable for ELISA and Western.
"Affinity pure" antibodies have been over the antigen-affinity column and recommended for immunohistochemical applications.
"Control peptides" can not be used for Western as they are very short peptides. They are intended for ELISA or antibody competition studies.

List of Related Products

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